

Citation for published version:

Holland, R, Tillett, W, Korendowych, E, Cavill, C, Waldron, N, Brooke, M & McHugh, NJ 2018, 'Validation of the Psoriatic Arthritis Impact of Disease (PsAID) Questionnaire and its potential as a single-item outcome measure in clinical practice', *Annals of the Rheumatic Diseases*, vol. 77, no. 3, pp. 343-347.
<https://doi.org/10.1136/annrheumdis-2017-211996>

DOI:

[10.1136/annrheumdis-2017-211996](https://doi.org/10.1136/annrheumdis-2017-211996)

Publication date:

2018

Document Version

Peer reviewed version

[Link to publication](#)

This is the author's accepted manuscript of an article published in *Annals of the Rheumatic Diseases* on 15 November 2017 as Holland R, Tillett W, Korendowych E, et al. Validation of the Psoriatic Arthritis Impact of Disease (PsAID) Questionnaire and its potential as a single-item outcome measure in clinical practice *Annals of the Rheumatic Diseases*. The version of record is available via <http://doi.org/10.1136/annrheumdis-2017-211996>. (C) The Authors, 2018.

University of Bath

Alternative formats

If you require this document in an alternative format, please contact:
openaccess@bath.ac.uk

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Title Page

Validation of the Psoriatic Arthritis Impact of Disease (PsAID) Questionnaire and its potential as a single item outcome measure in clinical practice

Richard Holland, William Tillett, Eleanor Korendowych, Charlotte Cavill, Nicola Waldron, Melanie Brooke and Neil J McHugh

Authors:

Dr Richard John Holland (Corresponding author)

1. Royal National Hospital for Rheumatic Diseases, Royal United Hospitals, Bath, United Kingdom
Postal address: Suite 419, RPAH Medical Centre, 100 Carillon Avenue, Newtown, NSW 2042,
AUSTRALIA

Email: dr-richardholland@gmail.com

Phone: +61 (02) 95504822

Dr William Tillett

1. Royal National Hospital for Rheumatic Diseases, Royal United Hospitals, Bath, United Kingdom
2. University of Bath, Department of Pharmacy and Pharmacology, Bath, United Kingdom

Dr Eleanor Korendowych

1. Royal National Hospital for Rheumatic Diseases, Royal United Hospitals, Bath, United Kingdom

Mrs Charlotte Rosemary Cavill

1. Royal National Hospital for Rheumatic Diseases, Royal United Hospitals, Bath, United Kingdom

Ms Nicola Mary Waldron

1. Royal National Hospital for Rheumatic Diseases, Royal United Hospitals, Bath, United Kingdom

Ms Melanie Brooke

1. Royal National Hospital for Rheumatic Diseases, Royal United Hospitals, Bath, United Kingdom

Professor Neil John McHugh

1. Royal National Hospital for Rheumatic Diseases, Royal United Hospitals, Bath, United Kingdom
2. University of Bath, Department of Pharmacy and Pharmacology, Bath, United Kingdom

Word Count: 2865

Keywords: Psoriatic Arthritis, Outcomes research, Disease activity, Patient perspective, DMARDs (biologic)

ABSTRACT

Objectives: The Psoriatic Arthritis Impact of Disease questionnaire (PsAID) is a recently developed patient reported outcome measure (PROM) of disease impact in psoriatic arthritis (PsA). We set out to assess the validity in an independent cohort of patients, estimate the minimally important difference for improvement and explore the potential of individual components of the PsAID in clinical practice.

Methods: Data were collected prospectively for a single-centre cohort of PsA patients. Construct validity was assessed by Spearman correlation with other PROMs and reliability by intraclass correlation coefficient (ICC) at 1 week. Sensitivity to change at 3 months was determined by the standardised response mean (SRM) in those patients with active disease requiring a change in treatment.

Results: A total of 129 patients (mean±SD age 52.1±13.3, 57% female, disease duration 10.2±8 years) completed the baseline questionnaires and assessments. The mean baseline PsAID12 score was 3.92±2.26 with an ICC of 0.91 (95%CI 0.87-0.94). The standard error of measurement was 0.51 and the minimal detectable change was 1.41. There was strong correlation ($r \geq 0.70$) with most of the PROMs studied and moderate correlation with clinical outcomes ($r = 0.40-0.57$). The SRM of the PsAID12 was 0.74 (95%CI 0.45-0.97). There was strong correlation with individual PsAID items and their corresponding PROM questionnaires ($r \geq 0.67$).

Conclusion: The PsAID is a reliable, feasible and discriminative measure in patients with psoriatic arthritis. The good responsiveness of the PsAID and strong correlation of individual items with other PROMS represents an opportunity to reduce questionnaire burden for patients in studies and clinical practice.

Keywords: Psoriatic Arthritis, Outcomes research, Disease activity, Patient perspective, DMARDs (biologic)

INTRODUCTION

Psoriatic Arthritis (PsA) is a chronic inflammatory arthropathy affecting up to 30% of patients with skin or nail psoriasis,[1]. Psoriasis is a complex disease, and has a multitude of clinical manifestations including skin and nail disease, dactylitis, enthesitis, peripheral arthritis, and axial disease. This complexity has resulted in the development of a number of disease activity indices to best capture the clinical manifestations of disease, all of which perform similarly and use a 'biomedical model' for determining disease activity,[2]. Disease activity and damage contribute to reduced physical and psychosocial health-related quality of life, with significant social and economic impact,[3].

Patient reported outcome measures (PROMs) have been found to be a reliable indicator of baseline status, change during treatment and are predictive of long-term outcome,[4-6]. The updated core domain set for PsA includes Patient Global Assessment (PGA), physical function (such as the Health Assessment Questionnaire, HAQ), fatigue and health related quality of life in the inner core,[7]. A recent literature review indicated that pain, PGA and HAQ were frequently measured in clinical trials, however other measures of how the patient feels or functions, such as fatigue and sleep, were rarely reported,[8]. The Short-Form 36 (SF-36), whilst a recognised measure of the economic impact of disease, is long and the interpretation of the score is complex. The HAQ has also been shown to change with disease duration and less reliably reflects disease activity in well-established disease,[9].

A EULAR taskforce developed a questionnaire to calculate a score reflecting the impact of psoriatic arthritis from the patients' perspective, termed the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire,[10]. Development of this questionnaire was driven by the patient perspective and involved 12 patient research partners from 12 countries all with personal experience of PsA. The taskforce determined 12 domains important to health and well-being, including fatigue, functional capacity, sleep and coping. The PsAID questionnaire was validated with more than 470 patients, and had good face validity and good generalizability and also correlated strongly with patient global assessment. The questionnaire has been divided into two scores; the PSAID12 uses all 12 items and was designed to be used in clinical practice, and the PSAID9 uses the first 9 items and was designed to be used in clinical trials. The authors commented that further validation in independent cohorts would be necessary, in particular sensitivity to change.

The Outcome Measures in Rheumatology (OMERACT) filter,[11] assess the applicability of a measure and looks at three aspects: Truth, Discrimination and Feasibility. A measure is useful if it measures what is intended, is reliable and sensitive, and can be applied easily. The PsAID has been designed to

conform to these principals, but requires further validation, in particular regarding sensitivity to change in comparison with other outcome measures, both clinical and patient reported. The PsAID includes items related to work, fatigue and physical function, all components of the inner core in the PsA Core Domain Set. A single questionnaire could therefore be used in routine clinical care to assess these domains, reducing patient burden. The aim of the study was to further investigate the PsAID in a new cohort to determine reliability, construct validity, sensitivity to change, to validate the minimal clinically important improvement and investigate the correlation of individual questions of the PsAID with established PROMS.

METHODS

Study Design

Data were collected prospectively from patients attending the Royal National Hospital for Rheumatic Diseases, Bath UK, from July 2015 until January 2017. The cohort was divided into two groups based on disease activity, with the data from group two used to determine sensitivity to change. Patients with stable disease not requiring a change in treatment (patient and physician opinion) were recruited to group one. Patients with active disease requiring a change in treatment were recruited to group two. Clinical measures and PROs including the PsAID were completed at baseline by both groups and the PsAID questionnaire was repeated at one week and returned by post. Patients in group two attended for follow-up 3 months after a change in treatment. For each patient, written informed consent was obtained, and the study was approved by the relevant ethics committee.

Inclusion criteria

To be eligible for the study, patients had to fulfil Classification of Psoriatic Arthritis (CASPAR) diagnostic criteria for PsA[12]. For patients in group two, an intensification of therapy was defined as: (i) an increase in the dose of the current conventional synthetic disease modifying anti-rheumatic drug(s) (csDMARDs); (ii) initiation of new csDMARD(s); (iii) initiation of a new, or change of the current, biological DMARD (bDMARD). Patients were excluded from the study if they were under the age of 18, were unable to speak and read English, had an additional inflammatory disease other than Psoriatic disease, or severe, unstable co-morbidities that could influence the PROMs.

Data collection

Demographic data were collected at baseline including age, gender, disease duration, smoking status, body mass index (BMI), and the presence or absence of erosive disease on x-ray. At baseline (both groups) and at 3 months (group two) patients completed the Health Assessment Questionnaire –

Disability Index (HAQ-DI,[13]), EuroQol questionnaire (EQ5D-5L,[14,15]), Psoriatic Arthritis Quality of Life questionnaire (PsAQoL,[16]), Dermatology Life Quality Index (DLQI,[17]), Work Productivity and Activity Impairment: Specific Health Problem Questionnaire (WPAI:SHP,[18]) and visual analogue scale (VAS) scores for patient global assessment (PGA), and joint global assessment (JtGA). All patients underwent a full clinical assessment at baseline, and a 66/68 swollen (SJC) and tender (TJC) joint count, dactylitis score, Leeds enthesitis index (LEI,[19]), Bath nail score,[20], Psoriasis Activity and Severity Index (PASI,[21]), physician global VAS (PhGA) and C-reactive protein (where possible) were recorded. The modified Composite Disease Activity Index (mCPDAI,[22]) was used as a composite measure of disease activity.

Patients in group two had a further clinical assessment at follow-up, and in addition were asked “which statement best describes your arthritis today compared to 3 months ago?” a) Overall my condition is improved; b) Overall, my condition is stable; c) Overall, my condition is worse. If patients indicated their condition had improved, they were also asked to rate the improvement as somewhat significant, moderately significant, or very significant. The PsAID questionnaire was completed at baseline, 1-week and 3-months (follow-up, group two only).

Statistical Analysis

Internal consistency of the PsAID scoring tool was evaluated using Cronbach’s α coefficient, with a value greater than 0.7 indicating consistency. Relative reliability of the PsAID was tested with the intraclass correlation coefficient (ICC, two-way mixed model absolute agreement), and variability was assessed using the Bland-Altman method,[23]. Absolute reliability was determined by the standard error of measurement (SEM), indicating the variability in scores upon repeated testing. The SEM was determined using $SEM = SD \times \sqrt{(1 - reliability)}$,[24]. The minimal detectable change (MDC), representing the magnitude of change required to exceed the measurement error, was calculated for the 95% confidence interval as $MDC = SEM \times 1.9 \times \sqrt{2}$,[25].

Construct validity was assessed using Spearman rank correlation coefficient as the PROM scores were not normally distributed (Shapiro-Wilk test). Sensitivity to change was calculated using the standardised response mean (SRM, the mean change between baseline and 3 months divided by the SD of the change) with the analysis done on a per protocol basis. An SRM greater than 0.8 is considered large. Confidence intervals were calculated by boot-strap.

The Minimal Clinically Important Improvement (MCII) was estimated using receiver operating characteristic curves, plotted using improvement versus no improvement as the outcome, and the minimal clinically relevant improvement was computed as the change score that had maximal sensitivity whilst maintaining a specificity of 0.80. This measure indicates the degree of change that 80% or more of patients would indicate as important.

The correlation between individual items of the PsAID questionnaire and specific patient-reported outcome questionnaires was evaluated. The domains studied were fatigue (FACIT-fatigue, compared with item 2 of the PsAID questionnaire), skin disease (DLQI, compared with item 3), work (WPAI:SHP, compared with item 4 and item 11), function (HAQ, compared with item 5) and quality of life (PsAQoL, compared with the PsAID12). To enable direct comparison with the PsAID items, the studied PROM questionnaires were transformed to a 0-10 scale. In the case of the FACIT-Fatigue, where higher scores indicate less fatigue, the scale was reversed so that a score of 0 indicated no fatigue and 10 indicated maximum fatigue. Correlation was determined using Spearman rank correlation coefficient. Bland-Altman plots with 95% upper and lower limits of agreement were constructed to examine the differences, using both absolute differences (score A – score B) and relative differences (score A – score B/mean%)[26]. Statistical analysis was performed using SPSS version 22.0.

RESULTS

A total of 159 patients were screened and recruited to the study; 129 patients satisfactorily completed the required baseline questionnaires and assessments. Demographic data for the cohort is presented in Table 1. The mean±SD baseline PsAID12 score was 3.92±2.36 and the mean baseline PsAID9 score was 4.11±2.40. The mean re-test PsAID 12 score was 3.55±2.26 and the mean re-test PsAID9 score was 3.72±2.30. Cronbach's alpha was 0.95 and the intraclass correlation coefficient (ICC) was 0.91 (95% CI 0.87-0.94) and 0.91 (0.86-0.94) for the PsAID12 and PsAID9 respectively indicating excellent reliability. Corresponding values for group 1 only were Cronbach's alpha 0.96, ICC 0.92 (0.87-0.96) and 0.92 (0.86-0.95) for PsAID12 and 9 respectively. There were very few missing items (<0.5%) indicating excellent feasibility. The variability in test-retest scores is shown in Figure 1. There was no proportional bias. The SEM was 0.51 and the minimal detectable change was 1.41.

Table 1. Baseline demographics for the total cohort and the sensitivity to change arm

| | Total Cohort (n=129) | Sensitivity to Change (n=53) |
|----------------|----------------------|------------------------------|
| Age, Mean ± sd | 52.1 ± 13.3 | 48.0 ± 14.0 |

| | | |
|---------------------------------|----------------|----------------|
| Disease duration, Mean \pm sd | 10.2 \pm 7.8 | 9.5 \pm 8.8 |
| BMI, Mean \pm sd | 29.2 \pm 5.9 | 28.9 \pm 5.5 |
| Sex, M (%) | 55 (42.6) | 22 (41.5%) |
| Erosive disease, Yes (%) | 50 (38.8) | 19 (35.8%) |
| Smoker, Yes (%) | 19 (14.7) | 8 (15.1%) |
| SJC, Median (range) | 1 (0-15) | 2 (0-15) |
| TJC, Median (range) | 6 (0-54) | 8 (0-50) |
| PASI, Median (range) | 0.2 (0-7.9) | 0.3 (0-7.9) |
| LEI, Median (range) | 0 (0-6) | 0 (0-4) |
| Dactylitis, Median (range) | 0 (0-7) | 0 (0-4) |
| mCPDAI, Median (range) | 3 (0-10) | 3 (0-10) |

There was strong correlation between the PsAID and most PROMs as shown in Table 2, with Spearman's rank correlation coefficient greater than 0.60. The strongest correlation was with the EQ5D Index score (-0.87), followed by the BASDAI and FACIT-Fatigue. There was moderate correlation between the PsAID and joint counts (Spearman's rho of 0.57 and 0.40 for tender and swollen joint counts respectively) and mCPDAI score (0.57). There was no correlation between the PsAID score and the PASI, possibly due to the minimal skin disease in the patient population (mean PASI 0.6 indicating very mild skin disease).

Table 2. Association between PsAID and clinical and patient reported outcomes (Spearman correlation coefficient)

| | PsAID12 | PsAID12 (Males) | PsAID12 (Females) |
|-----------------|---------|-----------------|-------------------|
| EQ5D Index | -0.87 | -0.90 | -0.80 |
| BASDAI | 0.84 | 0.93 | 0.74 |
| FACIT-Fatigue | -0.84 | -0.80 | -0.86 |
| PsAQoL | 0.80 | 0.84 | 0.77 |
| Work Impairment | 0.75 | 0.75 | 0.67 |
| PGA | 0.70 | 0.76 | 0.60 |
| HAQ | 0.70 | 0.83 | 0.56 |
| EQ5D VAS | -0.70 | -0.83 | -0.57 |
| Presenteeism | 0.69 | 0.61 | 0.68 |
| DLQI | 0.36 | 0.39 | 0.36 |
| PhGA | 0.61 | 0.74 | 0.41 |
| TJC | 0.57 | 0.65 | 0.42 |
| mCPDAI | 0.57 | 0.63 | 0.44 |
| SJC | 0.40 | 0.46 | 0.29 |
| PASI | -0.075 | 0.03 | -0.01 |

The PsAID score did not change significantly when stratified by disease duration, age, BMI, or the presence or absence of erosive disease (data not shown). Notably, the PsAID score was higher in females with a mean score of 4.44 ± 2.13 vs 3.23 ± 2.50 in females and males respectively, with females scoring significantly higher in 8 of the 12 items. This compared similarly to the other recorded PROMs in this cohort, with higher scores seen in females for all patient reported outcome measures except DLQI. The correlation with PROMs and clinical outcomes was also stronger in males than in females (Table 2).

To determine the minimal clinically important improvement, an ROC curve was constructed using improved (overall, my condition has improved) vs not improved (overall, my condition is stable or worse) as the outcome (Figure 2, supplementary data). The AUC was 0.821. The change in PsAID score with greatest sensitivity whilst maintaining a specificity of 80% was 1.25 (sensitivity 61%, specificity 80%). Furthermore, an ROC curve was constructed with improvement defined as a relative improvement in PsAID score at 3 months of 30%. Again, an absolute change score of 1.25 had the greatest sensitivity and specificity (74% and 77% respectively). In this cohort, using the previously proposed cut-off of three to define a MCII¹⁰ specificity was 100% but sensitivity was only 29%.

Sensitivity to change was assessed in those patients who remained on increased therapy at the time of their follow-up assessment. The SRM of the PsAID12 was 0.74 (95%CI 0.45-0.97). In comparison, the SRM of the mCPDAI was 0.71 (0.35-1.01).

The individual items of the PsAID questionnaire typically scored higher than the PROM questionnaires (Table 3). There was strong correlation between PsAID item and corresponding PROM questionnaire, with Spearman correlation coefficients >0.70 (Table 4, supplementary data), with the strongest correlation seen in the domains of fatigue and skin disease. Variability was assessed using Bland-Altman plots (see supplementary data, Figures 3-13). There was significant variability in the scores, with upper limits of agreement ranging from 2.9 to 5.22 and lower limits of agreement -4.0 to -1.97. Bland-Altman plots of the percentage difference in scores showed that at mean scores greater than five the PsAID item score more closely approximated the PROM questionnaire score.

Table 3. PROM score vs PsAID Item score and differences

| | Score (mean \pm sd) | Difference between scores (mean(95%CI)) | 95% Upper and Lower Limits of Agreement of the scores |
|--|-----------------------|---|---|
| | | | |

| | | | |
|----------------------------------|------------|-----------------------|-------------|
| FACIT-Fatigue vs PsAID Item 2 | 4.04 ± 2.5 | 0.96 (0.63-1.29) | 4.25, -2.33 |
| | 5.00 ± 3.1 | | |
| DLQI vs PsAID Item 3 | 0.87 ± 1.2 | 1.50 (1.17 – 1.82) | 4.96, -1.97 |
| | 2.39 ± 2.6 | | |
| WPAI-SHP vs PsAID Item 4 | 2.85 ± 2.8 | 0.70 (0.18 – 1.21) | 4.56, -3.17 |
| | 3.54 ± 2.9 | | |
| HAQ vs PsAID Item 5 | 3.20 ± 2.6 | 1.02 (0.62 – 1.41) | 5.22, -3.19 |
| | 4.30 ± 2.8 | | |
| PsAQoL vs PsAID12 | 4.53 ± 3.0 | -0.53 (-0.85 – -0.22) | 2.90, -4.00 |
| | 3.97 ± 2.4 | | |

DISCUSSION

We have demonstrated that the PsAID questionnaire is a reliable measure of the impact of disease in a UK cohort of patients with psoriatic arthritis, with the 9-item and 12-item questionnaires performing similarly. The questionnaire was also feasible with a very low number of missing items. With a mean difference of 0.10 (95% CI -0.10 – 0.31) there was only minor variability in baseline and 1-week scores despite including patients with both stable and active disease. Unlike similar instruments used in RA (the Rheumatoid Arthritis Impact of Disease, RAID,[13]) there was no obvious floor effect.

The significant difference between mean scores for males and females has not been previously demonstrated for the PsAID questionnaire and requires further investigation. In this cohort, baseline demographics were similar between males and females, although males had significantly longer disease duration (mean 11.8 vs 9.1 years). Females had higher tender (11.1 vs 6.4) and swollen (2.6 vs 1.8) joint counts as well as higher mCPDAI scores (3.4 vs 2.6), but after adjusting for disease activity the difference in PSAID score remained significant. A similar difference was noted with the RAID score, as well as other PROMs in psoriatic arthritis including HAQ,[276], and may need to be taken into account when interpreting scores. Di Carlo et al assessed construct validity and reliability in an Italian cohort, and noted similar results to this study. In addition, PsAID scores were higher in patients with concomitant fibromyalgia. Although not reviewed in our cohort, co-existent fibromyalgia may have contributed to the gender difference found in our study.

The PsAID questionnaire correlated strongly with other patient reported outcome measures, with the strongest correlation with the EQ5D-index score. This is perhaps not surprising given the EQ5D-Index questionnaire includes the domains of mobility, function, usual activities, pain and mental health, which are similar to the domains assessed in the PsAID questionnaire. The correlation with the FACIT-fatigue is interesting, and ongoing fatigue despite adequate control of psoriatic disease may be may

be one of the main drivers of disease impact. The moderate correlation with clinical outcomes is also expected, as domains such as work, sleep and fatigue are major determinants of disease impact yet are not captured by clinical scores.

The minimal clinically important improvement of 1.25 in the PsAID score in this cohort is significantly less than the MCII of 3.0 in the preliminary validation of the PsAID questionnaire. In this study, the majority of patients had a change of DMARD (increased dose or additional agent), and only 29% had a change of biological DMARD (change or new biologic agent). This may have resulted in a lower mean change in PsAID score in this study compared to the study by Gossec et al in which 50% of patients were commenced on a biological DMARD. In addition, patients were included if they had a change in DMARD dose, which may have also affected the MCII determined in this study.

The PsAID was found to be sensitive to change, with a standardised response mean of 0.74 which was greater than the standardised response mean for the mCPDAI score (0.71), although this was lower than the SRM as determined in the preliminary validation of the PsAID (Gossec et al). Although not a measure of disease activity, the PsAID questionnaire could be a useful outcome measure to guide treatment.

The individual items of the PsAID questionnaire correlated strongly with the corresponding PROM questionnaire, particularly between item two (fatigue) and the FACIT-Fatigue and item three (skin) and the DLQI. When examining the differences using Bland-Altman plots, we found that the individual PsAID item was typically scored higher than the PROM. The upper and lower limits of agreement were clinically significant, with a mean upper limit of agreement of 4.4 and a mean lower limit of agreement of -2.9. Given the wide 95% levels of agreement seen in this study, the individual PsAID items may not be able to accurately estimate a PROM score. As the PsAID items are disease specific, and questionnaires such as the HAQ and FACIT-Fatigue are not, co-morbid conditions in some patients may have contributed to some of this variability. However, the strong linear relationship between individual items and corresponding PROMs does indicate that the PsAID questionnaire is able to highlight domains that are of most concern for a patient, particularly as the percentage difference between the scores was significantly less at higher mean scores. The PsAID questionnaire could therefore be used to tailor treatment at an individual level, targeting the domains that are of most concern for the patient. This would eliminate the need for multiple PROM questionnaires at every visit, reducing questionnaire burden and fatigue especially in routine outpatient care.

The limitations of this study ~~are~~^{are} the low number of patients in the sensitivity to change arm who had a significant response to a change in treatment, and a formal calculation of sample size was not performed. Additional data from interventional clinical trials, particularly of biologic DMARDs, will be useful in confirming the ability of the PsAID to detect change and further validating the MCII.

In summary, the PsAID is a reliable, feasible and valid measure of the impact of disease in patients with psoriatic arthritis. It can be used in patient with both stable and active disease, correlates well with clinical and patient reported outcome measures, and can be used to tailor treatment to the individual.

REFERENCES

1. Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis* 2005;64(suppl2):ii14-ii17.
2. Helliwell PS, FitzGerald O, Fransen J, et al. The development of candidate composite disease activity and responder indices for psoriatic arthritis (GRACE project). *Ann Rheum Dis* 2013;72:986–91.
3. Boehncke W-H, Menter A. Burden of disease: psoriasis and psoriatic arthritis. *Am J Clin Dermatol* 2013;14(5):377-388.
4. Scoggins JF, Patrick DL. The use of patients reported outcomes instruments in registered clinical trials: evidence from ClinicalTrials.gov. *Contemp Clin Trials* 2009;30:289–92.
5. Kalyoncu U, Dougados M, Gossec L, et al. Reporting of patient-reported outcomes in recent trials in rheumatoid arthritis: a systematic literature review. *Ann Rheum Dis* 2009;68:183–90.
6. Kirwan JR, Bartlett SJ, Beaton DE, et al. Updating the OMERACT filter: implications for patient-reported outcomes. *J Rheumatol* 2014;41(5):1011-5.
7. Orbai, AM, de Wit, M, Mease PJ, et al. Updating the Psoriatic Arthritis (PsA) Core Domain Set: A Report from the PsA Workshop at OMERACT 2016. *J Rheumatol* 2017 Feb1pii: jrheum.160904 [epub ahead of print].
8. Palominos PE, Gaujoux-Viala C, Fautrel B, et al. Clinical outcomes in psoriatic arthritis: A systematic literature review. *Arthritis Care Res* 2012;64:397–406.
9. Husted JA, Tom BD, Farewell VT, et al. A longitudinal study of the effect of disease activity and clinical damage on physical function over the course of psoriatic arthritis. *Arthritis Rheum* 2007;56(3):840-849.
10. Gossec L, de Wit M, Kiltz U et al. A patient-derived and patient-reported outcome measure for assessing psoriatic arthritis: elaboration and preliminary validation of the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire, a 13-country EULAR initiative. *Ann Rheum Dis* 2014;73:1012-1019.
11. Boers M, Brooks P, Strand CV, et al. The OMERACT Filter for Outcome Measures in Rheumatology. *J Rheumatol* 1998;25(2):198-199.
12. Taylor W, Gladman D, Helliwell P, et al. Classification criteria for psoriatic arthritis: development of new criteria from a large international study. *Arthritis Rheum* 2006;54:2665-2673.
13. Fries JF, Spitz PW, Young DY. The dimensions of health outcomes: the health assessment questionnaire, disability and pain scales. *J Rheumatol* 1982;9:789–93.
14. Janssen MF, Pickard AS, Golicki D et al. Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. *Qual Life Res* 2013;22(7):1717-27.
15. van Hout B, Janssen MF, Feng YS, et al. Interim scoring for the EQ-5D-5L: mapping the EQ-5D-5L to EQ-5D-3L value sets. *Value Health* 2012;15(5):708-15.
16. McKenna S, Doward L, Whalley D, et al. Development of the PsAQoL: a quality of life instrument specific to psoriatic arthritis. *Ann Rheum Dis* 2004;63(2):162-169.
17. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)--a simple practical measure for routine clinical use. *Clin Exp Dermatol* 1994;19(3):210-6.
18. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoeconomics* 1993;4(5):353-65.
19. Healy PJ, Helliwell PS. Measuring clinical enthesitis in psoriatic arthritis: assessment of existing measures and development of an instrument specific to psoriatic arthritis. *Arthritis Rheum* 2008;59(5):686-91.

20. Wallis D, Waldron N, McHugh N, et al; Basic Science 299. TNF inhibitors in psoriatic arthritis: effects on nail disease—an observational study. *Rheumatology (Oxford)* 2013;52(suppl_1):i135-i172.
21. Fredriksson T, Pettersson U. Severe psoriasis – Oral therapy with a new retinoid. *Dermatologica* 1978;157:238–244.
22. FitzGerald O, Helliwell P, Mease P et al. Application of composite disease activity scores in psoriatic arthritis to the PRESTA data set. *Ann Rheum Dis* 2012;71:358-362.
23. Bland J, Altman D. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986;1(8476):307-10.
24. De Vet HC, Terwee CB, Ostelo RW, et al. Minimal changes in health status questionnaires: distinction between minimally detectable change and minimally important change. *Health Qual Life Outcomes* 2006;4:54.
- ~~25.~~ Beckerman H, Roebroeck ME, Lankhorst GJ, et al. Smallest real difference, a link between reproducibility and responsiveness. *Qual Life Res* 2001;10:571–578.
- ~~25-26.~~ Pollock MA, Jefferson SG, Kane JW et al. Method comparison –a different approach. *Ann Clin Biochem* 1992; 29: 556–60.
- ~~26-27.~~ Lee JJ, Pope JE. The Effects of Sex on Patient Reported Outcomes in Inflammatory Arthritis and Connective Tissue Diseases. *Open J Rheumatol Autoimmune Dis* 2013;3:59-64.

Formatted: Font: Italic

Acknowledgements:

The authors wish to acknowledge the support of Arthritis Australia and the Australian Rheumatology Association. We also wish to acknowledge the staff and patients of the Royal National Hospital for Rheumatic Disease involved in the study.

Competing Interests:

Dr. Holland reports grants from Arthritis Australia, during the conduct of the study; grants from Celgene, outside the submitted work.

Dr. McHugh reports personal fees from Abbvie, grants and personal fees from Celgene, personal fees from Eli Lilly, outside the submitted work.

Dr. Tillett reports grants and personal fees from Abbvie, grants and personal fees from Celgene, personal fees from UCB, outside the submitted work.

Mrs. Cavill reports grants from Abbvie, grants from Celgene, outside the submitted work.

The remaining authors do not have any disclosures.

Funding:

Dr Richard Holland was supported by an award from Arthritis Australia and the Australian Rheumatology Association.

Contributorship:

Conception and design of the study: RH, WT, NJM, MB; acquisition and/or analysis of data: RH, WT, EK, CC, NW, NJM; Drafting the work or revising it critically for important intellectual content: RH, WT, EK, CC, NW, MB, NJM; Final approval of the version to be published: RH, WT, EK, CC, NW, MB, NJM.

Ethical Approval:

The study was conducted according to the principles of the Declaration of Helsinki and ethical approval was obtained from the NRES Committee Yorkshire & The Humber - Bradford Leeds. All patients included in this study gave full written informed consent for participation.

FIGURES:

Figure 1. Bland-Altman plot of the difference in baseline and 1-week PsAID scores